JUL 2 6 2000

K001466

510(k) Summary of Safety and Effectiveness

Trade Name:	Silicone VoCoM® System
Common Name:	Vocal Cord Medialization Implant
Classification Name:	Ear, Nose & Throat Synthetic Polymer Material (§ 874.3620)
Official Contact:	Alicia E. Farage Senior Regulatory Affairs Specialist Smith & Nephew, Inc. ENT Division 2925 Appling Road Bartlett, TN 38133
Telephone:	(901) 373-0200
Telefax:	(901) 373-0242
Date Prepared:	May 9, 2000.

The Silicone VoCoM system is identical, other than material, to the current VoCoM implants and shims marketed by Smith & Nephew, Inc., ENT Division. It is also similar to the Montgomery® Thyroplasty Implant System marketed by Boston Medical Products and the PhonoForm™ Silicone Blocks marketed by Medtronic Xomed Surgical Products, Inc.

This product has the same indication for use as all of the predicate devices: for medialization thyroplasty in patients with unilateral vocal cord paralysis to improve voice quality.

The Silicone VoCoM system is made from silicone as are the Montgomery Thyroplasty Implant System and the PhonoForm Silicone Blocks. This is the same material as the current offerings by Boston Medical and Xomed. The current VoCoM system is made of dense hydroxylapatite.

All three predicate systems utilize special instrumentation as does the Silicone VoCoM system.

The Silicone VoCoM system has the most of the same design features as the previously cleared VoCoM system. The only addition is the through hole to allow suturing within the thyroid cartilage fenestra. It is available in 3-8 mm implants and shims that allow 0-3 mm offset. The carveable offering is scored in 1mm increments for referencing during hand trimming.

The Montgomery System is available in 10 sizes: 6 mm - 10 mm for females and 8 mm-12 mm for males. The PhonoForm Silicone Blocks are available in a right, left, and wedge configuation. Left and Right blocks have a height range of 2.5-10.5 mm. The wedge has a maximum height of 12.5 mm.

Differences between the Silicone VoCoM implants and shims and the predicate devices should not affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 2000

Ms. Alicia E. Farage
Sr. Regulatory Affairs Specialist
Smith & Nephew, Inc.
2925 Appling Rd.
Barlett, TN 38133

Re: K001466
Trade Name: Silicone VoCoM® Implant System
Regulatory Class: II
Product Code: 77MIX
CFR: 874.3620
Dated: May 26, 2000
Received: May 31, 2000

Dear Ms. Farage:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number: K001466
Device Name: **Silicone VoCoM® Implants**

Indications For Use:

The Smith & Nephew, Inc., ENT Division, Vocal Cord Medialization System is indicated for medialization thyroplasty in patients with unilateral vocal cord paralysis to improve voice quality.

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K001466